K012525

OCT - 4 2001

Thermo DMA

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510 (k) Summary

This Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter: Thermo DMA, Inc.

Address: 845 Avenue G East
Arlington, Texas 76011

Contact Person: Thomas Dollar, Manager of Regulatory Affairs

The assigned 510(k) number is K012525

Product Code: LCP, Assay, Glycosylated Hemoglobin

Device Name: Thermo DMA Fructosamine Assay

Device Class: II

Predicate Device: Sigma Diagnostics Fructosamine (Procedure No. 465)

Description and Intended Use: Thermo DMA's fructosamine reagent is intended for the in vitro quantitative determination of Fructosamine in human serum.

Clinical Significance [2,5]:
In monitoring diabetic patients there may be a need for assays that are more sensitive than glycated hemoglobin to shorter-term alterations in average blood glucose levels. Fructosamine is reported to serve as an index to the average glycemic state during the previous several weeks. Therefore the test may represent a useful aid for short-term glycemic control related to diabetes management.

Methodology [1-4]:
Under alkaline conditions, analytes with Amadori rearrangements, such as Fructosamine, have reducing activity that can be differentiated from other reducing substances. In the presence of carbonate buffer, fructosamine rearranges to the eneaminol form, which reduces Nitroblue tetrazolium (NBT) to a formazan. The absorbance at 530 nm is measured at two time points and the absorbance change is proportional to the fructosamine concentration. A 10-minute incubation is employed to allow fast reacting interfering reducing substances to react. Removal of endogenous glucose is not required due to the fact that a pH of greater than 11 is required for glucose to reduce NBT.

Method Comparison: Comparison studies were carried out on a Hitachi 704 automated clinical chemistry analyzer using a commercially available calibrator as a reference. Serum samples were assayed in parallel and the results compared by the least regression method. The following statistics were obtained:

Number of Sample Pairs: 49
Range of Sample Results: 1.25 - 5.10 mmol/L
Mean of Results (Sigma): 2.17
Mean of Results (Thermo DMA): 2.17
Slope: 0.980
Intercept: 0.039
Correlation Coefficient: 0.998

Precision:

Within Run

	Level 1	Level 2
Number of Data Points	20	20
Mean (mmol/L)	2.21	3.47
SD (mmol/L)	0.02	0.04
CV(%)	1.1%	1.1%

Total

	Level 1	Level 2
Number of Samples	10	10
Mean (mmol/L)	2.21	3.42
SD (mmol/L)	0.04	0.04
CV(%)	1.6%	1.2%

Sensitivity: Based on an instrument resolution of A = 0.001, the Thermo DMA Fructosamine reagent assay has a sensitivity of 0.02 mmol/L. Sensitivity studies based on serial dilutions of control material yield a sensitivity of 0.1 mmol/L.

Reportable Range: A study of 31 human serum samples, asymtomatic with respect to Fructosamine provided an observed range of 1.6 - 2.6 mmol/L. Linearity studies conducted by Thermo DMA demonstrated acceptable performance up to 6.0 mmol/L.

Specificity: Interference studies conducted by Thermo DMA determined the following;

1. Bilirubin interference - At a fructosamine level of 2.5 mmol/L a positive interference was observed at bilirubin levels greater than 2.8 mg/dL. At a fructosamine level of 4.1 mmol/L a positive interference was observed at bilirubin levels greater than 13.5 mg/dL.
2. Hemoglobin interference - Hemolyzed samples are not recommended for use in this assay. At a fructosamine level of 2.5 mmol/L a negative interference was observed at hemoglobin levels greater than 83 mg/dL.

Specificity: - (continued)

3. Ascorbic acid interference - At a fructosamine level of 2.5 mmol/L a negative interference was observed at ascorbic acid levels greater than 4 mg/dL. At a fructosamine level of 4.2 mmol/L a negative interference was observed at ascorbic acid levels greater than 8 mg/dL.
4. Lipemic interference - At a fructosamine level of 2.5 mmol/L a positive interference is observed at Triglyceride levels greater than 242 mg/dL.

Reference Ranges: Some overlap occurs between ranges for healthy and diabetic individuals. Jury and Dunn[4] reported a range of 1.9 - 2.9 mmol/L for 55 non-diabetic subjects, with the 95th percentile being 2.7 mmol/L. A range of 2.1 - 5.0 mmol/L, meanwhile was found for a group of diabetic subjects with 10% of the values being below 2.7 mmol/L.

Conclusion: Analysis of the comparative measurements presented in the 510(k) submission for this reagent, together with linearity and precision data collected in data presented demonstrates the Thermo DMA Fructosamine assay is safe and effective. No significant differences exist between the results obtained on samples analyzed utilizing the Thermo DMA Fructosamine when compared to those obtained when utilizing the predicate device in these studies.

References:

1. Howe JEA, Browning MCK, Fraser CG: Assay of serum fructosamine that minimizes standardization and matrix problems: Use to assess components of biological variation. Clin Chem 33:269, 1987
2. Armbruster DA: Fructosamine: Structure, analysis and clinical usefulness. Clin Chem 33:2153, 1987
3. Lloyd D, Marples J: Simple colorimetry of glycated serum protein in a centrifugal analyzer. Clin Chem 30:1686, 1984
4. Jury DR, Dunn PH: Laboratory assessment of a commercial kit for measuring fructosamine in serum. Clin Chem 33:158, 1987
5. Johnson RN, Metcalf PA, Baker JR: Fructosamine: A new approach to the estimation of serum glycosylprotein. An index of diabetic control. Clin Chem Acta 127:87, 1982

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Thomas Dollar
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OCT - 4 2001

Re: k012525
Trade/Device Name: Thermo DMA Fructosamine Assay
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: July 31, 2001
Received: August 6, 2001

Dear Mr. Dollar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
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Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K012525

Device Name: Thermo DMA Fructosamine Assay

Indications For Use: This reagent is intended for the in vitro quantitative determination of Fructosamine (glycated protein) in human serum when run on the Hitachi 704 automated chemistry analyzer. Measurements of fructosamine are used as an aid for short-term glycemic control related to diabetes management.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kesia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012525

Prescription Use OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)
